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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/686,499	10/11/00	CURTISS	R 3116-1192

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HM22/0406

 EXAMINER

SHAHNAN-SHAH, K

 ART UNIT

1645

 PAPER NUMBERDATE MAILED: 04/06/01 4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/686,499	CURTISS, ROY	
	Examiner Khatol S Shahnan-Shah	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims 1-44 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
1. received.
2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: \_\_\_\_\_

***Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22 are, drawn to a microorganism and a vector, classified in class 435, subclass 252.1.
  - II. Claims 23-29 are, drawn to a method of selecting a gene in microbial cell, classified in class 435, subclass 471.
  - III. Claims 30-36 are, drawn to a vaccine, classified in class 424, subclass 190.1.
  - IV. Claims 37-44 are, drawn to a method of gene therapy, classified in class 424, subclass 93.1.

2. The inventions are distinct, each from the other because of the following reasons:

Groups II and IV are drawn to different methods. The claims of group II are drawn to a method of selecting a gene; those of group IV are drawn to a method of gene therapy. The inventions are shown to be distinct because they are drawn to distinct methods, which differ in the method objectives, method steps, reagents and material used.

Groups I-III are drawn to structurally and functionally distinct products. The claims of group I are drawn to a microorganism and a vector, those of group III are drawn to a vaccine. The inventions are shown to be distinct because they are drawn to distinct products made by different methods and they are physically and functionally distinct molecules.

Groups II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

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made by another and materially different process (MPEP § 806.05(f)). In the instant case the method can be used to select desired genes in human or animal cells.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Election of species*

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

- Election 1. Choose one of the species in claim 3.
- Election 2. Choose one of the antigens in claims 5, and 18.
- Election 3. Choose one of the species in claim 6.
- Election 4. Choose one of the species in claim 20.
- Election 5. Choose one of the species in claim 25.
- Election 6. Choose one of the species in claim 27.
- Election 7. Choose one of the species in claim 28.
- Election 8. Choose one of the species in claim 32.
- Election 9. Choose one of the species in claim 34.

Election 10. Choose one of the species in claim 39.

Election 11. Choose one of the species in claim 40.

Election 12. Choose one of the species in claim 43.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 12, 23, 30, 38 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol 4/15/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

4/15/01